

JUN - 2 2003

K031135  
DADE BEHRING

DADE BEHRING INC.  
P.O. Box 6101  
Newark, DE 19714

**Summary of Safety and Effectiveness Information**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Submitter's Name:** Lorraine Piestrak  
Dade Behring Inc.  
P.O. Box 6101  
Newark, DE 19714-6101

**Date of Preparation:** April 8, 2003

**Name of Product:** Glucose Flex® reagent cartridge (GLUC)

**FDA Classification Name:** Glucose Test System

**Predicate Device:** Dimension® Glucose Method (K860021)

**Device Description:**

**Intended Use:** The Glucose Flex® reagent cartridge (GLUC) for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of glucose in human serum, plasma, urine, and cerebrospinal fluid.

**Comparison to Predicate Device:**

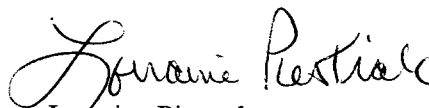
<u>Item</u>	<u>GLUC Flex® reagent cartridge</u>	<u>GLU Flex® reagent cartridge</u>
Sample Type	Serum, plasma, urine, and cerebrospinal fluid	Serum, plasma, urine, and cerebrospinal fluid
Technology	Enzymatic: Hexokinase- glucose-6 phosphate dehydrogenase	Enzymatic: Hexokinase- glucose-6- phosphate dehydrogenase
Detection	Bichromatic endpoint measurement- NADH (340 & 383 nm)	Bichromatic endpoint measurement- NADPH (340 & 383 nm)
Reaction Time	120 seconds	180 seconds
Reagents	Liquid	Tablets

**Comments on Substantial Equivalence:**

Split sample comparison between the GLUC Flex® reagent cartridge on the Dimension® clinical chemistry system and the GLU Flex® reagent cartridge also on the Dimension® clinical chemistry system gave the following correlation statistics, when tested with clinical patient samples:

Sample Type	Slope	Intercept	Correlation Coefficient	n
Serum/Plasma	1.01	0.01	0.999	162
Urine	1.01	-1.05	1.000	64
Cerebrospinal Fluid	1.00	-0.54	1.000	70

**Conclusion:** The Glucose Flex® reagent cartridge (GLUC) is substantially equivalent in principle and performance to the Glucose Flex® reagent cartridge (GLU) assay based on the split sample comparison discussed above.



Lorraine Piestrak  
Regulatory Affairs and Compliance Manager  
Date: April 8, 2003



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN - 2 2003

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Lorraine Piestrak  
Regulatory Affairs and Compliance Manager  
Dade Behring Inc.  
P.O. Box 6101  
Newark, DE 19714

Re: k031135  
Trade/Device Name: Glucose Flex<sup>®</sup> reagent cartridge (GLUC)  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Code: CFR  
Dated: April 8, 2003  
Received: April 9, 2003

Dear Ms. Piestrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

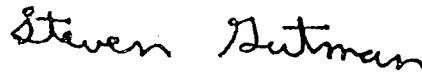
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

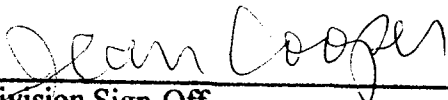
Enclosure

### Indications For Use Statement

**Device Name:** Glucose Flex® reagent cartridge (GLUC)

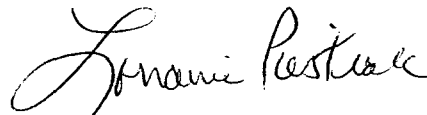
#### Indications for Use:

The Glucose Flex® reagent cartridge for the Dimension® clinical chemistry system is an *in vitro* diagnostic device intended to quantitatively measure glucose in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

K031135



Lorraine Piestrak  
Regulatory Affairs and  
Compliance Manager

April 8, 2003

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-the-counter Use \_\_\_\_\_

(Optional format 1-2-96)